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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,580	06/20/2000	Gary L. Griffiths	018733/0987	5842

22428 7590 11/03/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

JONES, DAMERON L

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/597,580

Applicant(s)

GRIFFITHS ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-42, 44 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 37, 38, 44, 51 and 52 is/are rejected.
- 7) ☒ Claim(s) 2-5, 7-36, 39-422, 46-50, 53, and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### COMMENTS/NOTES

1. The following action is necessary in order to clarify the instant invention.

### ACKNOWLEDGMENTS

2. The Examiner acknowledges receipt of the amendment filed 8/12/04 wherein claims 1, 37, and 38 are amended and claims 6, 43, and 45 are canceled. In addition, the Examiner acknowledges the acceptable terminal disclaimer filed 8/12/04.

**Note:** Claims 1-5, 7-42, 44, and 46-54.

### RESPONSE TO APPLICANT'S RESPONSE/ARGUMENTS

3. The Applicant's arguments filed 8/12/04 to the rejection of claims 1-42, 44, and 46-54 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive for reasons of record. Therefore, all outstanding rejections are hereby WITHDRAWN.

### NEW GROUNDS OF REJECTION

#### **112 First Paragraph Rejection**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 37, 38, 44, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for first and second

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therapeutic agents selected from radionuclides, cytokines, drugs, toxins, and boron addends, does not reasonably provide enablement for all therapeutic agents. In addition, the instant invention is not enabled for all marker substances produced by or associated with a tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to compositions comprising a therapeutic naked antibody, a first conjugate, a first and second therapeutic agent, drug-polymer conjugate, a PEG-drug conjugate, a drug-liposome conjugate and optionally, a clearing agent.

(2) State of the prior art

The references of record do not indicate which specific therapeutic agents are useful with the claimed invention. Likewise, the references do not indicate which specific marker substance produced by or associated with a tumor are useful with the instant invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claims 1, 37, and 38 encompass a vast number of possible therapeutic agents and marker substances. Applicant's specification does not enable the public to make or use such a vast number of possible therapeutic agents and marker substances.

(4) Level of predictability in the art

The art pertaining to the therapeutic agents and marker substances is highly unpredictable. Determining the various types of therapeutic agents or class of therapeutic agents and the marker substances require various experimental procedures and without guidance that is applicable to all compositions, there would be little predictability in performing the claimed invention. Hence, there is little predictability in performing the claimed invention, absent some guidance.

(5) Amount of direction and guidance provided by the inventor

Independent claims 1, 37, and 38 encompass a vast number of therapeutic agent and marker substances. Applicant's limited guidance does not enable the public to prepare such a numerous amount of therapeutic agents and marker substances. There is no directional guidance for the marker substances or therapeutic agents, except for agents selected from the group consisting of radionuclides, cytokines, drugs, toxins, and

boron addends. Hence, there is no enablement for all possible permutations and combinations of the therapeutic agents and marker substances.

(6) Existence of working examples

Independent claims 1, 37, and 38 encompass a vast number of therapeutic agents and marker substance. Applicant's limited working examples do not enable the public to prepare such a numerous amount of therapeutic agents and marker substances. While Applicant's claims encompass a plethora of possible marker substances and therapeutic agents, the specification provides agents selected from the group consisting of radionuclides, cytokines, drugs, toxins, and boron addends.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible marker substances and therapeutic agents known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

**112 Second Paragraph Rejection**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 37, 38, 44, 51, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what marker substance or group of substances is/are being claimed. In addition, one cannot readily ascertain what therapeutic agents Applicant is intended to be compatible with the instant invention. Hence, Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

**CLAIM OBJECTIONS**

8. Claims 2-5, 7-36, 39-42, 46-50, 53, and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Note:** The claims are distinguished over the prior art of record for reasons of record in the office action mailed 2/12/04.

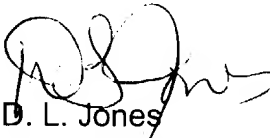
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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

October 29, 2004